

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

CARDIAQ VALVE TECHNOLOGIES,  
INC.,

Plaintiff,

v.

NEOVASC INC. and NEOVASC TIARA  
INC.,

Defendants.

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Civil Action No. 14-cv-12405-ADB

**MEMORANDUM AND ORDER**

October 31, 2016

BURROUGHS, D.J.

From June 2009 through April 2010, Plaintiff CardiAQ Valve Technologies, Inc. (“CardiAQ”) hired Defendant Neovasc Inc. (“Neovasc”) to help construct prototypes of CardiAQ’s transcatheter mitral valve implant (“TMVI”) device. CardiAQ alleges that Neovasc breached the parties’ non-disclosure agreement (“NDA”) and misappropriated CardiAQ’s trade secrets by using CardiAQ’s confidential information to develop its own competing TMVI device. On May 19, 2016, following a two-week trial, a jury found for CardiAQ as to some, though not all, of its claims. The jury returned a verdict finding that Neovasc: (1) breached the NDA; (2) breached the duty of honest performance in the NDA; and (3) misappropriated three of CardiAQ’s six claimed trade secrets. [ECF No. 483]. The jury awarded CardiAQ \$70,000,000 in damages for Neovasc’s theft of trade secrets, with no additional damages for the contract breaches.

The Court has already resolved several post-trial motions. On May 27, 2016, the Court granted Neovasc's motion for judgment as a matter of law with respect to CardiAQ's Chapter 93A claim, finding that Neovasc's alleged wrongful acts had not occurred "primarily and substantially within the commonwealth" of Massachusetts, as is required under the statute. Mass. Gen. L. Ch. 93A, § 11. [ECF No. 495]. On July 28, 2016, the Court denied both parties' renewed motions for judgment as a matter of law with respect to CardiAQ's duty of honest performance claims, declining to overturn the jury's finding that Neovasc had breached the duty of honest performance with regard to the NDA, but not with the parties' purchase orders. [ECF No. 529].

On August 15, 2016, the Court held oral argument on the remaining post-trial motions: CardiAQ's motions for enhanced damages and injunctive relief [ECF Nos. 513, 516] as well as Neovasc's motions for a new trial on damages and trade secrets 4-6 [ECF Nos. 511, 520]. The Court also heard argument on CardiAQ's inventorship claim, which was left for the Court rather than the jury to decide.

Finally, on October 19, 2016, in anticipation of an appeal, Neovasc filed motions and a supporting memorandum [ECF Nos. 571-574] seeking the *Pro Hac Vice* admission of three additional attorneys. CardiAQ opposed the motions on October 24, 2016 [ECF No. 578].

This Order resolves all of the outstanding motions, as well as CardiAQ's inventorship claim. For the reasons stated herein: (1) CardiAQ's motion for enhanced damages [ECF No. 513] is GRANTED IN PART; (2) CardiAQ's motion for injunctive relief [ECF No. 516] is GRANTED IN PART; (3) Neovasc's motion for a new trial on damages [ECF No. 522] is DENIED; (4) Neovasc's motion for a new trial on trade secrets 4-6 [ECF No. 521] is DENIED; (5); Dr. Quadri and Mr. Ratz are to be added as co-inventors of U.S. Patent No. 8,579,964; and

(6) Neovasc's motions for the *Pro Hac Vice* admission of new attorneys [ECF Nos. 571-573] are DENIED as MOOT.

## **I. Background**

### **a. Procedural Background**

In its original complaint, filed on June 6, 2014 [ECF No. 1], as well as its amended complaint, filed on January 15, 2015 [ECF No. 64], CardiAQ brought the following seven claims against Neovasc: (1) correction of inventorship under 35 U.S.C. § 256; (2) breach of the NDA; (3) breach of the implied covenant of good faith and fair dealing in the NDA and purchase orders;<sup>1</sup> (4) fraud; (5) misappropriation of trade secrets under Mass. Gen. L. ch. 93 §§ 42, 42A and the common law; (6) violation of Mass. Gen. L. ch. 93A § 11; and (7) injunctive relief.

In April 2016, the Court granted Neovasc's motion for summary judgment as to the fraud count, finding that Neovasc did not have an affirmative duty to disclose its competitive activities to CardiAQ, and therefore did not commit fraud by failing to disclose such activity once it began. [ECF No. 417]. The Court, however, denied Neovasc's motion for summary judgment as to the inventorship and Chapter 93A counts. Id.

The next month, this action proceeded to trial. Over the course of the two-week trial, the two founders of CardiAQ—Brent Ratz and Dr. Arshad Quadri—testified, as did Rob Michiels, the former CEO of CardiAQ; Randy Lane, Vice President of Research and Development at Neovasc; and Alexei Marko, CEO of Neovasc. The jury also heard the deposition of testimony of several fact witnesses that were not present at trial, including: Colin Nyuli, an intellectual property manager and former project engineer at Neovasc; Krista Neale, the manager of new

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<sup>1</sup> Because both the NDA and the parties' purchase orders are governed by Canadian law, at trial, CardiAQ's claims for breach of the covenant of good faith and fair dealing under Massachusetts law were advanced under the analogous duty of honest performance under Canadian law.

technology development and former project engineer at Neovasc; Kathleen Hung, a project manager at Neovasc; Dr. Michael Mack, a former member of CardiAQ's scientific advisory board; and Glen Rabito, a senior manager of research and development at Edwards Lifesciences and a former engineering manager and research and development project leader at CardiAQ.

In addition, three experts testified for CardiAQ. Dr. Joseph Bavaria, Vice Chairman of the Department of Cardiovascular Surgery at the University of Pennsylvania and Director of the Transcatheter Valve Program at the University of Pennsylvania, testified as to the anatomy of the heart and specifically, the mitral valve. Dr. Rick Hillstead, a Fellow on the Council of Clinical Cardiology within the American Heart Association, testified generally about the development of medical devices and the customs and practices of vendors, suppliers, and development houses in the medical device field. Finally, Michael J. Wagner, the managing director at Litinomics, Inc., a financial and economic consulting firm, testified as to damages, opining that the reasonable royalty Neovasc owed to CardiAQ was \$90 million, based on a hypothetical negotiation taking place in 2010. Three experts also testified for Neovasc. Steven Little, a cardiologist at Houston Methodist Hospital and the medical director of its valve clinic, testified regarding cardiac imaging and the anatomy of the mitral valve, as well as the interaction of CardiAQ's and Neovasc's respective devices within the native mitral valve anatomy. Karl R. Leinsing, a mechanical engineer who develops medical devices, testified regarding CardiAQ's trade secret claims and Neovasc's Tiara development. Lastly, Carla Mulhern, managing principal in the Washington D.C. office of Analysis Group, testified as to damages, and opined that correcting for various errors in Mr. Wagner's analysis, the appropriate royalty figure was no more than \$2 million.

The jury returned a split verdict. [ECF No. 483]. The verdict form contained eight questions. The first four concerned CardiAQ's breach of contract claims. The jury was asked to determine whether CardiAQ had proven, by a preponderance of the evidence that Neovasc had: (1) breached the NDA; (2) breached the duty of honest performance in the NDA; and (3) breached the duty of honest performance in the purchase orders. If the jury answered yes to any of these three questions, they were instructed to then determine the amount of money CardiAQ should receive for Neovasc's breach(es). The jury answered yes to the first two questions, but no to the third: Neovasc had breached the NDA as well as the duty of honest performance in the NDA, but not the purchase orders. As to the fourth question, the jury found that CardiAQ should not receive any money for Neovasc's breaches.

Next, the jury was asked to determine if Neovasc had misappropriated CardiAQ's trade secrets. At trial, CardiAQ maintained that Neovasc had misappropriated six of its trade secrets, and the verdict form asked the jury to make a separate finding as to each one. The six alleged trade secrets were originally identified by CardiAQ during discovery, and were described in trial exhibit 1157. The alleged trade secrets were:

1. CardiAQ's Rev. C Prototype Design [Tr. Ex. 1157 at 1-5];
2. CardiAQ's Rev. D Prototype Design [Tr. Ex. 1157 at 5-10];
3. CardiAQ's Rev. E Prototype Design [Tr. Ex. 1157 at 10-14];
4. A transcatheter replacement mitral valve prosthesis design that includes an expandable metal frame for supporting a tricuspid, one-way valve, the expandable metal frame sized for placement in a human native mitral valve space, where the prosthesis is configured for mitral valve implantation without relying exclusively on radial force but rather by engaging the native mitral valve annulus on the atrial side of the native mitral valve and by anchoring the prosthesis on the ventricular side of the native mitral valve annulus [Tr. Ex. 1157 at 14-17];
5. The CardiAQ Mandrel [Tr. Ex. 1157 at 18]; and

6. CardiAQ's Transcatheter Mitral Valve Implantation Development History  
[Tr. Ex. 1157 at 18].

The jury found that that Neovasc had misappropriated trade secrets 4-6, but not trade secrets 1-3, and that CardiAQ should receive \$70 million as damages for Neovasc's misappropriation.

The jury was also asked to make factual determinations with respect to the two counts— inventorship and Chapter 93A—reserved for the Court. The jury found that CardiAQ had proven (1) by a preponderance of the evidence that Neovasc engaged in unfair and deceptive acts or practices; and (2) by clear and convincing evidence that the two founders of CardiAQ contributed to the conception of Neovasc's U.S. Patent No. 8,579,964 (the "'964 Patent").

**b. Factual Background**

Below is a summary of facts adduced at trial that are relevant to the outstanding issues in this case:

Neovasc and CardiAQ's business relationship began on June 4, 2009, after Brian McPherson, the Vice President of Operations and President of the Surgical Products division at Neovasc, sent an unsolicited email to CardiAQ co-founder Brent Ratz advertising Neovasc's products and services. [Tr. Day 3, 183:7-20; Tr. Ex. 349]. The email stated that Neovasc was the only supplier of "custom pericardial tissue actively supporting companies developing minimally invasive heart valves," and that he was confident CardiAQ could benefit from Neovasc's services. [Tr. Ex. 349] Mr. McPherson attached a 15-page presentation to the email, describing Neovasc's services. Id. at 3-17.

Mr. Ratz responded that same day to indicate his interest in learning more about Neovasc. [ECF No. 304-7 at 32]. Before speaking with Mr. McPherson about a potential business relationship, Mr. Ratz suggested that the parties execute a Non-Disclosure Agreement. Id. Mr.

Ratz emailed Mr. McPherson CardiAQ's standard agreement, and Mr. McPherson responded that he would rather use Neovasc's. Id. On June 4, 2009, the parties executed Neovasc's Non-Disclosure Agreement (the "NDA"), agreeing that the recipient of "Confidential Information" could not use or disclose such information for "any purpose other than evaluating the proposed business relationship." [Tr. Ex. 371].<sup>2</sup> The parties agreed that the recipient of Confidential Information could not "directly or indirectly, disclose any Confidential Information to any third party or use the Confidential Information for its own benefit or for the benefit of any third party." Id. The NDA had a five-year term, and was governed by the laws of the Province of British Columbia. Id. The NDA was executed via email and signed by Mr. Ratz and Neovasc CEO Alexei Marko. [Tr. Day 3, 188:1-14; Tr. Ex. 371].

At the time Mr. McPherson reached out to CardiAQ, CardiAQ was a start-up developing a TMVI device—a prosthetic heart valve delivered through a catheter to replace a malfunctioning native mitral valve. Mitral regurgitation, one of the most common forms of heart disease, can be treated by replacing the mitral valve, but, currently, the only way to replace the mitral valve is through open heart surgery. By June 2009, CardiAQ, had developed a prototype of its TMVI device, intended to replace the mitral valve through a catheter procedure, rather than open heart surgery.

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<sup>2</sup> Confidential Information is defined in the NDA as "any oral or written information received from the Discloser which is not generally known to the public . . . Confidential Information includes, by way of example and not limitation, information of a technical nature such as trade secrets; manufacturing processes or devices; current products or products under development; research subjects; methods and results; matters of a business nature such as information about cost, margins, pricing policies, markets, sales, suppliers and customers; product, marketing or strategic plans; financial information; personnel records and other information of a similar nature." [ECF No. 64, Ex. B].

CardiAQ's device consists of three elements: the frame, the delivery catheter, and the tissue valve. [Tr. Day 3, 15:20-23]. Between June 2009 and April 2010, Neovasc worked with CardiAQ to manufacture the tissue valve element. [Tr. Day 3, 16:1-3]. During this time, CardiAQ and Neovasc entered into several purchase orders (the "Purchase Orders"), in which they agreed to the work Neovasc would perform. [See e.g., ECF No. 64, Ex. D]. CardiAQ would send metal frames to Neovasc's Vancouver facility [Tr. Day 4, 36:15-37:2; Tr. Ex. 1205], and Neovasc would attach tissue to the frame and assemble the final TMVI prototype. [Tr. Day 3, 24:23-25:2; Tr. Day 3, 35:1-2; Tr. Day 4, 26:1-3]. CardiAQ used the prototypes assembled by Neovasc for several animal studies. [Tr. Day 3, 25:3-9; Tr. Day 4, 48:10-12].

Over the course of the 10-month relationship, Mr. Ratz regularly exchanged emails and phone calls with Neovasc employees. Through these emails and phone calls, Neovasc employees, including engineer Randy Lane, learned about the specifications, ongoing animal testing, and development history of CardiAQ's TMVI device. [See e.g., Exs. 1171; 1179; 1193; 1197; 1214]. During this time, CardiAQ sent frames of its Rev. C, D, and E prototypes to Neovasc, which then attached the tissue valve element. [Tr. Day 3, 209:24-211:24; Tr. Day 4, 27:10-25; Tr. Day 4, 36:15-37:25].

On October 20, 2009, in the middle of CardiAQ and Neovasc's business relationship, Mr. Lane drew the first sketch of what would become Neovasc's own TMVI device, now known as the "Tiara." [Tr. Day 8, 99:10-12; Day 9, 67:9-17; Tr. Ex. 1121]. After sketching the concept in his lab notebook, Mr. Lane told Neovasc's CEO Alexi Marko about the idea [Tr. Day 8, 100:11-21], and Mr. Marko instructed Mr. Lane to proceed with an in-house mitral valve program, which he did. [Tr. Ex. 343; Tr. Day 8, 122:9-123:11]. Mr. Marko advised Mr. Lane not to tell CardiAQ about Neovasc's internal project, explaining in an October 21, 2009 email that, "when



appropriate we may need to disclose to [CardiAQ] that we are working on something, but let's cross that bridge when we come to it." [Tr. Ex. 343].

Neovasc and CardiAQ's business relationship ended in April 2010, after CardiAQ leased its own manufacturing facility in California and no longer needed Neovasc's services. [Tr. Day 4, 46:9-16; Tr. Day 7, 119:14-25; Tr. Day 9, 107:19-22]. Until Neovasc's relationship with CardiAQ ended in April 2010, Mr. Lane worked on both Neovasc's internal TMVI project and CardiAQ's valve assembly. [Tr. Day 9, 113:10-19]. Mr. Lane used the same lab notebook to document his development of Neovasc's valve and his assembly of CardiAQ's valve, at times including notes on adjacent pages. [Tr. Ex. 1121]. Neovasc did not restrict any of its engineers from working on both the Tiara project and the CardiAQ project, and several did. [Tr. Day 9, 113:14- 24].

In December 2009, Neovasc began to prepare its first patent application relating to the Tiara design. [Tr. Day 9, 107:23-108:5]. Neovasc filed the application on May 5, 2010 [Tr. Day 9, 107:23-25], naming Mr. Lane as the sole inventor. [Tr. Ex. 2756]. The U.S. Patent Office issued the '964 Patent on November 12, 2013, naming Mr. Lane and Colin Nyuli, a Neovasc employee who joined Neovasc in September 2010, as joint inventors. [Tr. Ex. 115]. The '964 Patent is a method patent for a transcatheter mitral valve prosthesis. Id.

Neovasc formally announced its internal TMVI project in a June 20, 2011 press release. [Tr. Ex. 347; Tr. Day 9, 206:11-17]. Since then, Neovasc's device has been implanted in over 100 animals. [Tr. Ex. 2533 at 57]. On February 3, 2014, Neovasc announced the first in-human implantation of its device by physicians at St. Paul's Hospital in Vancouver. [Tr. Ex. 2315]

Neovasc never told CardiAQ about its internal TMVI program. [Tr. Day 4, 51:14-18; Tr. Day 9, 112:23-113:1]. Mr. Ratz and Dr. Quadri first learned of Neovasc's development of a

TMVI device in December 2011, after Neovasc's patent application became public. [Tr. Day 3, 68:2-23; Day 4, 51:19-25]. Soon thereafter, in February 2012, counsel for CardiAQ contacted Mr. Marko to express concern that Neovasc may have incorporated CardiAQ's confidential information into its Tiara device, in violation of the NDA. [Tr. Ex. 1389]. In June 2014, after counsel for the parties exchanged multiple letters [see, e.g., Tr. Exs. 188, 1272, 2482], CardiAQ filed the instant action. Neither CardiAQ's nor Neovasc's TMVI devices have received regulatory approval, and both are currently in the clinical trial process.

## **II. CardiAQ's Motions**

CardiAQ's two pending motions request enhanced damages [ECF No. 513] and injunctive relief [ECF No. 516] in addition to the \$70 million already awarded by the jury. The motion for enhanced damages asks the Court to double the jury's \$70 million damages award. The motion for injunctive relief requests that the Court order Neovasc to: (1) destroy all information that CardiAQ sent to Neovasc between June 2009 and April 2010; (2) return to CardiAQ any CardiAQ prototypes, or portions thereof, that CardiAQ provided to Neovasc and that Neovasc still has in its possession, custody, or control; (3) without the written consent of CardiAQ, not prosecute claims covering subject matter that is either described in CardiAQ's Trade Secret Number 4, or described in claims of U.S. Patent No. 8,579,964, for which the Court determines Dr. Quadri and Mr. Ratz significantly contributed; and (4) with certain limitations, suspend all of its TMVI programs, including, but not limited to, its Tiara program, for eighteen months.

Following oral argument, CardiAQ submitted a supplemental memorandum regarding both motions [ECF No. 562], in which it suggested that the Court issue an injunction with contingencies, for example, that the injunction be contingent on whether or not Neovasc satisfies

the \$70 million verdict and further argued that the Court should enhance damages by at least 33%, or \$23.3 million. Neovasc responded to the supplemental memorandum on September 8, 2016. [ECF No. 567].

**a. Motion for Enhanced Damages**

CardiAQ's request for enhanced damages arises under Mass. Gen. L. ch. 93, § 42, which states that:

Whoever embezzles, steals or unlawfully takes, carries away, conceals, or copies, or by fraud or by deception obtains, from any person or corporation, with intent to convert to his own use, any trade secret, regardless of value, shall be liable in tort to such person or corporation for all damages resulting therefrom. *Whether or not the case is tried by a jury, the court, in its discretion, may increase the damages up to double the amount found.* The term "trade secret" as used in this section shall have the same meaning as is set forth in section thirty of chapter two hundred and sixty-six.

Mass. Gen. L. ch. 93, § 42 (emphasis added). This provision, which gives the Court discretion to double the jury's damages award in a trade secret case, has been applied sparingly in both state and federal court. In Data Gen. Corp. v. Grumman Sys. Support Corp., 825 F. Supp. 340, 343 (D. Mass. 1993), the court added \$9,000,000 to the jury's \$27,417,000 award after finding that defendant's misappropriation of trade secrets had been willful. In USM Corp. v. Marson Fastener Corp., 467 N.E.2d 1271, 1276–77 (Mass. 1984), the Massachusetts Supreme Judicial Court ("SJC") held that enhanced damages were inappropriate, where the jury had awarded damages based on defendant's profit (i.e. unjust enrichment) rather than plaintiff's lost profit. The SJC found that "[t]he reference to damages 'resulting from' a defendant's tortious act concerns the trade secret holders' loss of profit, and not, as here, a defendant's profit at a plaintiff's expense." Id. at 1285.

Neovasc argues that enhanced damages are precluded by the SJC's decision in USM Corp. "Absent damages for lost profits," according to Neovasc, "[CardiAQ] has no basis to seek

a new, novel construction of Ch. 93 § 42 inconsistent with the holding in USM.” [ECF No. 534 at 4]. CardiAQ counters that USM is inapposite, since it did not involve an award for reasonable royalties. The USM holding, according to CardiAQ, should be limited to cases in which the jury’s award disgorged the defendant’s profits, which was not the case here, where neither party has made any profit from their still-unapproved TMVI devices. [ECF No. 546 at 5-8].

The Court agrees with CardiAQ that the SJC’s decision in USM is distinguishable and does not preclude enhanced damages in this case. USM held that enhanced damages are not available under Ch. 93 § 42 where the damages awarded by the jury constitute “a defendant’s profit at a plaintiff’s expense.” USM, 467 N.E.2d at 1285. The SJC concluded that a defendant’s ill-gotten gains cannot be enhanced under the statute, since they are technically not damages “resulting from” the misappropriation. Id. USM does not apply to this case, where neither party has made any profit from their still unapproved TMVI devices, and the plaintiff pursued a reasonable royalty theory of damages. The reasonable royalty is the amount the parties would have hypothetically agreed on to grant the defendant the right to use plaintiff’s trade secrets. “The [reasonable royalty] determination remains one of damages to the injured party.” Fromson v. Western Litho Plate and Supply Co., 853 F.2d 1568, 1574 (Fed. Cir. 1988) (emphasis omitted), overruled on other grounds by Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 383 F.3d 1337, 1347 (Fed. Cir. 2004); see also Maxwell v. J. Baker, Inc., 86 F.3d 1098, 1109–10 (Fed. Cir. 1996) (“The objective of the reasonable royalty calculation is to determine the amount necessary to adequately compensate for an infringement.”). This is distinct from the award in USM, which disgorged defendant’s ill-gotten gains, and more analogous to lost profits, which USM said can be enhanced under the statute.

Further, Neovasc's misappropriation was willful, such that some amount of enhanced damages is appropriate. See Data Gen. Corp. v. Grumman Sys. Support Corp., 825 F. Supp. 340, 343 (D. Mass. 1993) (enhancing damages by 33% after finding that defendant's misappropriation of trade secrets had been willful). The same Neovasc employee—Randy Lane—was both the primary developer of Neovasc's Tiara device and the primary point of contact for CardiAQ. Neovasc took no steps to limit Lane, or any other employee, from working on both projects, despite the obvious conflict and potential for misuse.

Enhanced damages are particularly appropriate here, where the jury awarded reasonable royalty damages. It is unlikely that in 2009 or 2010, CardiAQ would have actually licensed its trade secrets to Neovasc, had Neovasc asked. The reasonable royalty, therefore, is based on a legal fiction and does not fully compensate CardiAQ. Because of Neovasc's misappropriation, which now cannot be undone, CardiAQ was compelled to license its technology to Neovasc, at the rate determined by the jury.

The Court therefore enhances damages by 30%, and Neovasc is ordered to pay \$21 million in addition to the \$70 million awarded by the jury.

**b. Injunctive Relief**

The permanent injunction requested by CardiAQ has four components, but the parties' arguments have largely focused on the single most punitive aspect of the proposed injunction—that with certain limitations, Neovasc be ordered to suspend all of its TMVI programs, including, but not limited to, its Tiara program, for eighteen months. CardiAQ contends that “without an injunction to reverse the unfair head start that Neovasc obtained by its breach and misappropriation, CardiAQ will continue to be irreparably harmed” [ECF No. 527 at 11] and that Neovasc will unfairly retain the competitive advantage it obtained by breaching the NDA and

misappropriating its trade secrets. Neovasc responds that the proposed injunction duplicates the money remedy sought and obtained by CardiAQ, that there is no basis for CardiAQ's 18-month head start argument, and that both the balance of hardships and public interest disfavor the injunction. [ECF No. 537-1]. In a supplemental memorandum filed after oral argument, CardiAQ added that an injunction is necessary and not duplicative, because there is a chance Neovasc will not be able to pay the \$70 million previously awarded by the jury. [ECF No. 562].

Based on "well-established principles of equity," to obtain a permanent injunction, "[a] plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). "The purpose of an injunction in a trade secret case is to protect the secrecy of the misappropriated information, eliminate the unfair advantage obtained by the wrongdoer and reinforce the public policy of commercial morality." Gen. Elec. Co. v. Sung, 843 F. Supp. 776, 778 (D. Mass. 1994). "[B]ecause of the public interest in promoting competition, punitive injunctions are ordinarily inappropriate in trade secret actions." Atl. Research Mktg. Sys., Inc. v. Troy, No. CIV.A.07-11576-PBS, 2010 WL 1904849, at \*8–9 (D. Mass. May 11, 2010) (quoting Jillian's Billiard Club of Am., Inc. v. Beloff Billiards, Inc., 619 N.E.2d 635, 638 (Mass. App. Ct. 1993)); see also Specialized Tech. Res., Inc. v. JPS Elastomerics Corp., No. HSCV200700200, 2011 WL 1366584, at \*16 (Mass. Super. Feb. 10, 2011), aff'd, 957 N.E.2d 1116 (Mass. App. Ct. 2011) ("[I]njunctions granted to prevent trade secret violations are not punitive and only rarely are truly permanent, as they must

be reasonable as to time and scope; what is reasonable depends on the facts of each particular case.”).

Having considered the four-factor test for a permanent injunction, the Court will not suspend Neovasc’s TMVI program for any amount of time. The \$70 million already awarded by the jury, together with the enhanced damages granted in this Order, adequately compensate CardiAQ for its injury. The proposed 18-month suspension would be duplicative of the monetary relief, and is not warranted given the uncertainty in the TMVI market, the impact the injunction would have on Neovasc, and the public’s interest in having access to a potentially life-saving technology.

The first two factors of the injunction analysis ask whether the plaintiff has suffered irreparable injury from the defendant’s actions and next, whether remedies available at law, such as monetary damages, are inadequate to compensate for the injury. “The first two of the four factors are satisfied on a showing of ‘substantial injury that is not accurately measurable or adequately compensable by money damages.’” CoxCom, Inc. v. Chaffee, 536 F.3d 101, 112 (1st Cir. 2008) (quoting Ross-Simons of Warwick, Inc. v. Baccarat, Inc., 217 F.3d 8, 13 (1st Cir. 2000)).

As noted earlier, CardiAQ pursued a reasonable royalty theory of damages. At trial, its expert testified that Neovasc would have agreed to pay CardiAQ \$90 million following a hypothetical negotiation between CardiAQ and Neovasc in 2010. The jury accepted some of this testimony by awarding CardiAQ \$70 million.

The reasonable royalty remedy is imperfect and necessarily inexact. See Bowling v. Hasbro, Inc., 582 F. Supp. 2d 192, 204–05 (D.R.I. 2008) (noting the “element of approximation and uncertainty inherent in the reasonable royalty rubric”). It assumes a fiction—that both parties

would have been willing to negotiate and agree to a royalty—in order to fashion a viable remedy in a case like this, where there are no other quantifiable damages.

In other cases, plaintiffs have sought a reasonable royalty for defendants’ past use of trade secrets, and then a permanent injunction to prevent any future use. See, e.g., Language Line Servs., Inc. v. Language Servs. Associates, Inc., 944 F. Supp. 2d 775, 783 (N.D. Cal. 2013) (“Language Line clarifies in its response that it seeks a reasonable royalty for past use of trade secrets . . . and a permanent injunction to prevent future misappropriation . . . .”); RKI, Inc. v. Grimes, 200 F. Supp. 2d 916, 926 (N.D. Ill. 2002) (“These cases are distinguishable from the case at hand because this Court did not award any damages for future use of the misappropriated information, but rather only awarded damages for the use and disclosure of Roll–Kraft’s trade secrets for the period before the injunction issued.”); cf. Bianco v. Globus Med., Inc., 53 F. Supp. 3d 929, 932, 938–39 (E.D. Tex. 2014) (“In patent cases in which a permanent injunction is sought, the Federal Circuit has held that a district court may impose a reasonable royalty on the defendant for future use of the patented invention in lieu of an injunction.”). Here, however, the \$90 million reasonable royalty requested by CardiAQ did not distinguish between past and future use of its trade secrets. The \$90 million figure approximated the amount Neovasc would have been willing to pay to use CardiAQ’s trade secrets indefinitely. This future-facing royalty overlaps with the injunction CardiAQ now seeks. The reasonable royalty is the amount Neovasc must pay for the right to use CardiAQ’s trade secrets, but the injunction would prevent Neovasc from using CardiAQ’s trade secrets at all.

Further, to arrive at the \$90 million figure, Mr. Wagner made several assumptions, including that, by misappropriating CardiAQ’s trade secrets and confidential information, Neovasc obtained an 18 month “head start” on its TMVI project—meaning that but for its



misappropriation, Neovasc would have been 18 months behind on the development of its TMVI device. He “assumed that Neovasc could have come up with an equivalent product to CardiAQ’s device, but it would have taken 18 months longer to do so without using the alleged CardiAQ trade secrets.” [Tr. Day 8 at 50:15-21]. His reasonable royalty thus placed a value on this 18-month head start. The requested injunction is premised on the same 18-month head start, and is therefore duplicative of the monetary relief already awarded. By now asking for Neovasc’s project to be suspended for 18 months, CardiAQ is trying to have it both ways—it has already received damages that approximate the value of the 18-month head start to Neovasc, and now it seeks an injunction that would eliminate the 18-month head start.

The third and fourth factors of the injunction analysis, the balance of the hardships and the public interest, each weigh against the injunction. First, the balance of the hardships disfavors granting the injunction. CardiAQ complains that if Neovasc is not enjoined, CardiAQ will have to compete with Neovasc for hospitals at which to perform studies, and for the attention of prominent surgeons known as “Key Opinion Leaders.” [ECF No. 517 ¶¶ 15-36]. The parties dispute whether this is true. Regardless, this potential hardship is far less severe than that Neovasc would face if the injunction were granted. The Court credits the testimony of Neovasc’s CEO that dozens of Neovasc employees would be laid off as a result of the injunction, given that more than half of Neovasc’s workforce is dedicated to the Tiara program. [ECF No. 538-13 ¶¶ 31–32]. Moreover, because of Neovasc’s small size and how central the Tiara is to its business, Neovasc might not remain as a going concern following the 18-month suspension. Id. ¶ 32.

The public would also be disserved by the injunction. As evidenced at trial, Neovasc and CardiAQ’s prototypes now differ in several respects and it is unknown which one will be most effective at treating malfunctioning mitral valves. No TMVI device has received regulatory

approval, and it is impossible to know which device(s) will or will not be approved. By imposing the 18-month injunction, the Court could potentially delay the progress of the one TMVI device that works, and thereby keep a lifesaving device off the market for an additional year-and-a-half. While there is a countervailing interest in protecting trade secrets and disincentivizing trade secret misappropriation, that interest is largely addressed by the damages Neovasc must pay, and is outweighed by the public's interest in getting the most effective TMVI device to the market as fast as possible.

“An injunction is a drastic and extraordinary remedy, which should not be granted as a matter of course.” Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139, 165–66 (2010). An injunction should not be granted where “a less drastic remedy” will suffice. Id. For the reasons explained above, the Court will not impose the 18-month injunction. The monetary relief already awarded by the jury, together with the enhanced damages ordered by the Court, largely compensate CardiAQ for its loss, and both the public interest and balance of the hardships disfavor the injunction.

In addition to the 18-month suspension, CardiAQ's motion for injunctive relief also requests that the Court order the following:

1. That within seven days, Neovasc destroy all information that CardiAQ sent to Neovasc between June 2009 and April 2010, including emails and attachments thereto, CAD files, engineering drawings, animal test results, design history information, as well as any work product that Neovasc generated that incorporates information contained in the foregoing, including the contents of any physical or electronic file that Neovasc may keep regarding CardiAQ, including the electronic CardiAQ folder referenced during trial.
2. That within seven days, Neovasc return to CardiAQ any CardiAQ prototypes, or portions thereof, that CardiAQ provided to Neovasc and that Neovasc still has in its possession, custody, or control, including but not limited to prototypes fabricated by Neovasc to test any CardiAQ prototype design.

3. That without the written consent of CardiAQ, Neovasc shall not in any patent application relating to U.S. Patent No. 8,579,964, prosecute claims covering subject matter that is either described in CardiAQ's Trade Secret Number 4, or described in claims of U.S. Patent No. 8,579,964 for which the Court determines Dr. Quadri and Mr. Ratz significantly contributed.

[ECF No. 516 ¶¶ 1-4].

The Court hereby approves the first two requests for relief. Neovasc is ordered to destroy all information that CardiAQ sent to Neovasc between June 2009 and April 2010 and to return to CardiAQ any CardiAQ prototypes, or portions thereof, that CardiAQ provided to Neovasc and that Neovasc still has in its possession, custody, or control, including but not limited to prototypes fabricated by Neovasc to test any CardiAQ prototype designs. Neovasc has no valid reason to keep this information. To the extent the information is public, which would allow Neovasc to use it even under the NDA, Neovasc can use public sources to obtain the information. Neither the public nor CardiAQ has an interest in Neovasc retaining CardiAQ's information and prototypes. Regardless of the fact, as Neovasc argues, that the NDA has expired, Neovasc does not have a right to retain CardiAQ's confidential information and the injunction is necessary to "protect the secrecy of misappropriated information, to eliminate the unfair advantage obtained by the wrongdoer, and to reinforce the public policy of commercial morality." Specialized Tech. Res., Inc. v. JPS Elastomerics Corp., No. HSCV200700200, 2011 WL 1366584, at \*16 (Mass. Super. Feb. 10, 2011), aff'd, 957 N.E.2d 1116 (Mass. App. Ct. 2011).

The Court will not order the third request for relief. As explained further below, see supra section IV.c., Mr. Ratz and Dr. Quadri should have been named as co-inventors on the '964 Patent—in collaboration with Mr. Lane, they made a significant contribution to the conception of the invention. The Court, however, cannot broadly extend this ruling to any "claims covering

subject matter that is either described in CardiAQ's Trade Secret Number 4 (Tr. Ex. 1157), or described in claims of U.S. Patent No. 8,579,964." [ECF No. 516 ¶ 4]. No patent other than the '964 Patent was ever at issue in this case, and CardiAQ cites no authority for the proposition that the Court can interfere with Neovasc's prosecution of pending and/or hypothetical patent applications.

That being said, just because this matter has been resolved, and judgment will soon be entered against Neovasc, Neovasc does not have free rein to claim CardiAQ's trade secrets and inventive concepts as its own. Any future TMVI patents that are issued to Neovasc will be subject to scrutiny under 35 U.S.C. § 256—consistent with the Court's ruling on the '964 Patent, Mr. Ratz and Dr. Quadri should not be excluded from any patents that they contributed to.

### **III. Neovasc's Pending Motions**

In its two pending motions, Neovasc requests a new trial on damages [ECF No. 522] and a new trial on CardiAQ's trade secret claims 4, 5, and 6. [ECF No. 521]. Neovasc claims that once the jury determined that Neovasc misappropriated some, but not all, of CardiAQ's trade secrets, Mr. Wagner's expert testimony regarding the reasonable royalty became useless and the jury had no basis for determining damages. In addition, Neovasc argues that the jury's finding of misappropriation with respect to trade secret claims 4, 5, and 6 is unsupported by the evidence and contrary to governing law.

Under Fed. R. Civ. P. 59, following a jury trial, a court may grant a motion for a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). The trial court may order a new trial if "the verdict is against the clear weight of the evidence, is based upon evidence that is false, or resulted from some trial error and amounts to a clear miscarriage of justice." Payton v. Abbott Labs, 780 F.2d 147, 152

(1st Cir. 1985). “[A] district court wields broad legal authority when considering a motion for a new trial,” but it cannot “displace a jury’s verdict merely because [it] disagrees with it or because a contrary verdict may have been equally . . . supportable.” Jennings v. Jones, 587 F.3d 430, 436 (1st Cir. 2009) (internal citations and quotations omitted). Absent an error of law, a judge should only set aside a jury verdict if “it is quite clear that the jury has reached a seriously erroneous result.” Milone v. Mocerri Family, Inc., 847 F.2d 35, 37–38 (1st Cir. 1988) (quotations omitted).

“In reviewing an award of damages, the district court is obliged to review the evidence in the light most favorable to the prevailing party and to grant remittitur or a new trial on damages only when the award exceeds any rational appraisal or estimate of the damages that could be based upon the evidence before it.” Wortley v. Camplin, 333 F.3d 284, 297 (1st Cir. 2003) (internal quotation marks omitted); see also Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1310 (Fed. Cir. 2009) (“A jury’s decision with respect to an award of damages must be upheld unless the amount is grossly excessive or monstrous, clearly not supported by the evidence, or based only on speculation or guesswork.”) (internal quotation marks omitted)). “[T]he jury is free to select the highest figures for which there is adequate evidentiary support, as long as the figure remains in the universe of acceptable awards.” Am. Steel Erectors v. Local Union No. 7, Int’l Ass’n of Bridge, Structural, Ornamental & Reinforcing Iron Workers, 815 F.3d 43, 58 (1st Cir. 2016) (internal citations and quotations omitted).

#### **a. Motion for a New Trial on Damages**

Most of the arguments raised by Neovasc in its motion for a new trial on damages were previously rejected, when the Court denied Neovasc’s motion to exclude Mr. Wagner’s testimony. [ECF No. 418]. In a motion in limine filed on the eve of trial, Neovasc argued that Mr. Wagner’s testimony on a reasonable royalty should be excluded because he: (1) had no basis

to assume that the information CardiAQ shared with Neovasc gave Neovasc an 18-month head start in the development of its Tiara device; (2) inappropriately incorporated financial information that arose after the date of the hypothetical negotiation; and (3) improperly relied on Neovasc's sales of securities to calculate a baseline royalty. [ECF Nos. 344, 346]. The Court rejected each of these arguments. First, the 18-month head start assumption, which was only one piece of Mr. Wagner's larger reasonable royalty analysis, did not warrant excluding Mr. Wagner's testimony, given that there was some evidence in the record to support the 18-month head start assumption, and that CardiAQ intended to present evidence at trial, through fact witnesses, to establish the facts assumed by Mr. Wagner. [ECF No. 418 at 6-7]. Second, though Mr. Wagner's Georgia-Pacific analysis included ex-post evidence, such as the value of the Tiara in 2015, he correctly calculated a reasonable royalty using a hypothetical negotiation date of March 2010, the date on which CardiAQ and Neovasc cut ties. Id. at 7-8. Accordingly, while Neovasc could challenge Mr. Wagner's use of 2015 data, it did not render his testimony inadmissible. Lastly, Mr. Wagner properly factored the proceeds from a Neovasc securities sale into his damages calculation since, unlike in the cases cited by Neovasc, he apportioned the value of the securities sale between CardiAQ's and Neovasc's contributions. Id. at 8-9. The Court concluded that Neovasc could challenge these three aspects of Mr. Wagner's opinion at trial, but that none warranted excluding his testimony. Id. at 6-9.

To the extent Neovasc attempts to rehash any of these arguments in its motion for a new trial, its efforts are unavailing. CardiAQ presented sufficient evidence at trial to support the 18-month head start assumption. It took CardiAQ about 20 months to develop the trade secrets at issue in this case, [Tr. Day 4, 127:16-19, 134:7-25], and Mr. Wagner was justified in assuming it would take Neovasc approximately the same amount of time. Over the course of the trial, the

jury heard considerable testimony about the value of CardiAQ's trade secrets, from which they could reasonably conclude that possessing them gave Neovasc an 18-month head start. The 18-month head start was supported by the evidence—namely, CardiAQ's own development time, as well as Dr. Ratz' testimony—and was not based on speculation or guesswork. Likewise, as the Court has already held, Mr. Wagner could consider data from 2015 to calculate a reasonable royalty based upon a hypothetical negotiation in 2010. At trial, Mr. Wagner testified as to all of the Georgia Pacific factors, several of which involve ex-post evidence, including: the “current popularity” of the infringing product, the “established profitability” of the product, and the “extent to which the infringer has made use of the invention.” Georgia-Pac. Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), modified sub nom. Georgia-Pac. Corp. v. U.S. Plywood-Champion Papers, Inc., 446 F.2d 295 (2d Cir. 1971); see also Lucent, 580 F.3d at 1333 (“[T]he hypothetical negotiation analysis ‘permits and often requires a court to look to events and facts that occurred thereafter and that could not have been known to or predicted by the hypothesized negotiators.’”) (quoting Fromson, 853 F.2d at 1575).

The one new argument raised by Neovasc in its motion for a new trial on damages, which was not raised in its pre-trial motion to exclude Mr. Wagner's testimony, is that the jury's split verdict on damages—finding that Neovasc misappropriated trade secrets 4-6, but not 1-3—renders Mr. Wagner's testimony useless. According to Neovasc, there was not evidence from which the jury could determine the value of trade secrets 4 and 6, since Mr. Wagner did not testify as to the reasonable royalty for each individual trade secret.<sup>3</sup> CardiAQ responds that it presented evidence that trade secrets 4 or 6 would command a \$90 million royalty. They point to Mr. Wagner's testimony, in which he stated that the combination of Trade Secrets 1 and 2, as

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<sup>3</sup> Mr. Wagner did not assign any value to trade secret 5, the Mandrel. [Tr. Day 8 at 68:11-17].

well as the individual Trade Secrets 3, 4, and 6 were each worth \$90 million. [Tr. Day 8, 16:22-25].<sup>4</sup> They also point to Mr. Ratz's testimony explaining that trade secrets 1 and 2 together, and trade secrets 3, 4, and 6 individually, all had the same value. [Tr. Day 4, 88:5-22].

Based on the evidence before it, including Mr. Wagner and Mr. Ratz' testimony, the jury rationally appraised the value of the misappropriated trade secrets, and Neovasc has not demonstrated that it is entitled to a new trial on damages. Mr. Wagner valued the trade secrets based on the challenges they solved and the head start they gave to Neovasc. It was not erroneous for Mr. Wagner to assume, or the jury to conclude, that the combination of trade secrets 1 and 2, as well as the individual trade secrets 3, 4, and 6 solved the same challenges and gave Neovasc the same head-start. Whether in the form of physical prototypes (trade secrets 1-3), design features (trade secret 4), or historical developments (trade secret 6), each disclosed the key inventive concepts behind CardiAQ's TMVI device, including its anchoring system, and how CardiAQ had gone about solving the challenges facing TMVI developers at the time.

**b. Motion for a New Trial on Trade Secrets 4, 5, and 6**

As the Court instructed the jury, for each trade secret claim, CardiAQ needed to prove by a preponderance of the evidence the following three elements: (1) that CardiAQ's information was a trade secret; (2) that CardiAQ took reasonable steps to preserve the secrecy of its information; and (3) that Neovasc used the trade secret through improper means. [Day 13 Tr. at 165:2-9]. In its motion for a new trial on trade secrets 4-6, Neovasc does not take issue with the Court's jury instructions. Rather, Neovasc contends that the "[t]he jury's finding of misappropriation with respect to TS Claims 4, 5, and 6 is unsupported by the evidence and

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<sup>4</sup> In his expert report, which was provided to Neovasc before trial, Mr. Wagner also stated that he was assigning equal value to trade secrets 1 and 2 together; trade secret 3 alone; trade secret 4 alone; and trade secret 6 alone. [ECF No. 363-2 at ¶ 13].



contrary to governing law.” [ECF No. 521 at 1]. Neovasc’s principal argument is that CardiAQ did not prove that trade secrets 4, 5, and 6 were in fact trade secrets, as defined under Massachusetts law and in the Court’s instructions.<sup>5</sup>

First, Neovasc argues that it is entitled to a new trial on trade secret number 4 since there was insufficient evidence to show that trade secret 4 was either a secret or a unified process, as is required of all trade secrets under Massachusetts law. Trade secret 4 described CardiAQ’s TMVI device generally. Trade secret 4 consists of:

A transcatheter replacement mitral valve prosthesis design that includes an expandable metal frame for supporting a tricuspid, one-way valve, the expandable metal frame sized for placement in a human native mitral valve space, where the prosthesis is configured for mitral valve implantation without relying exclusively on radial force but rather by engaging the native mitral valve annulus on the atrial side of the native mitral valve and by anchoring the prosthesis on the ventricular side of the native mitral valve annulus, where the prosthesis includes one or more of the following

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<sup>5</sup> In its jury instructions, the Court defined a trade secret as follows:

A trade secret may consist of any formula, pattern, device or combination of information which is used in business and which gives an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for machine or other device, or a list of customers. A trade secret is a process or device for continuous use in the operation of the business. It differs from other secret information in a business in that it is not simply information as to a single or ephemeral event in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees or the date fixed for the announcement of a new policy or for bringing out a new model or the like. The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in the industry cannot be appropriated by one as a secret.

A trade secret can exist in a combination of characteristics and components, even if some or all of the characteristics and components are in the public domain, as long as the unified process, design, and operation of the combination constitutes a unique combination that is a trade secret.

[Tr. Day 13 at 165-66].

additional features: a. Ventricular Anchors that Extend Between the Chordae, Capture the Native Leaflets, and Engage the Ventricular Side of the Native Mitral Annulus . . . b. Variable Strut Dimensions . . . c. Lower Atrial Profile . . . d. Larger Ventricular Cross-Sectional Dimension . . . e. V-Shaped Atraumatic Anchors . . . f. Mushroom-Shaped Locking Tabs

[Tr. Ex. 1157 at 14-17]. Neovasc’s motion for a new trial focuses on the six features listed at the end of trade secret 4. Neovasc claims that CardiAQ did not prove that these features were secret or that they constituted a unified process. According to Neovasc, “CardiAQ did not merely fail to establish secrecy of the individual features: it ultimately agreed that they were not secret,” and further that “CardiAQ offered no evidence that combining some or all of the features resulted in a unified process.” [ECF No. 521 at 5].

Neovasc’s motion for a new trial takes the six features listed at the end of trade secret number 4 out of context. CardiAQ did not claim that these features were themselves trade secrets. Instead, trade secret 4 consists of CardiAQ’s TMVI design, which contains one or more of the six listed features. As the Court instructed the jury without objection, “A trade secret can exist in a combination of characteristics and components, even if some or all of the characteristics and components are in the public domain, as long as the unified process, design, and operation of the combination constitutes a unique combination that is a trade secret.” [Tr. Day 13 at 166:4-9]. Though sugar is not a trade secret, a secret recipe containing sugar can be. Likewise, though mushroom-shaped locking tabs (one of the six listed features) may have been well-known in the industry and therefore not a trade secret, the jury could reasonably find that a TMVI device containing mushroom-shaped locking tabs was a trade secret.

Neovasc presented evidence that the individual elements of trade secret 4 were publically known, but not in the context of a fully conceptualized TMVI device. For example, Neovasc’s expert Mr. Leinsing cited to a patent on non-heart valve stents to show that variable strut

dimension was publicly known [Tr. Day 11, 109:2-12; Ex. 2075], to a patent for a transcatheter aortic valve to show that V-shaped, atraumatic anchors were publicly known [Tr. Day 11, 110:11-24; Ex. 2086], and to a patent on a stomach implant and aortic device to show that mushroom-shaped locking tabs were publicly disclosed. [Tr. Day 11, 110:25-111:18; Exs. 2079 and 2091]. Neovasc did not show, however, that these elements were included or combined in a previously disclosed transcatheter *mitral valve* device. CardiAQ revealed to Neovasc TMVI prototypes that embodied all of the features identified in CardiAQ's Trade Secret 4, [Tr. Day 4, 86:14-16; Tr. Day 7, 12:17-17:21], and the jury could reasonably conclude that a TMVI device with these features was both a secret and a unified process.<sup>6</sup>

Neovasc is also not entitled to a new trial on trade secret number 5. Trade secret number 5 was the CardiAQ Mandrel, a tool created by CardiAQ to help construct its TMVI device. During their business relationship, and pursuant to the NDA, CardiAQ gave the Mandrel to Neovasc, so that Neovasc could build CardiAQ's prototypes. Krista Neale, a Neovasc project engineer, admitted to using the Mandrel on an unrelated project after CardiAQ had cut ties with Neovasc. [Neale Depo. 115:04-117:18].

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<sup>6</sup> In support of its motion for a new trial on trade secret 4, Neovasc cites several trade secret cases that were decided on summary judgment, after the defendant challenged the adequacy of plaintiff's trade secret disclosures. In Sutra, Inc. v. Iceland Express, EHF for example, Judge Woodlock determined that plaintiff's trade secret disclosure, made during discovery, was "far too open textured to meet the test for an identifiable trade secret," where the plaintiff identified its alleged trade secret as the "operation, appearance, features and functionality" of its computer software. No. CIV.A. 04-11360-DPW, 2008 WL 2705580, at \*4 (D. Mass. July 10, 2008). Likewise, in Sit-Up Ltd. v. IAC/InterActiveCorp. the court granted summary judgment where the plaintiff failed to "describe the secret with sufficient specificity that its protectability [could] be assessed and to show that its compilation [was] unique." No. 05 CIV. 9292 (DLC), 2008 WL 463884, at \*10 (S.D.N.Y. Feb. 20, 2008). On summary judgment, Neovasc could have, but chose not to, challenge the adequacy of CardiAQ's trade secret disclosures. CardiAQ identified its trade secrets in August 2015, and Neovasc waited until after trial to argue that CardiAQ's disclosures were somehow inadequate. In any event, CardiAQ identified trade secret 4 with sufficient detail, describing its TMVI design with particularity.

Neovasc claims that it is entitled to a new trial on trade secret number 5 because CardiAQ ascribed no value to the Mandrel and because CardiAQ disclosed the Mandrel in an April 2010 patent application. The patent application, however, did not provide as much information as Neovasc received by holding the physical Mandrel and by viewing CAD files for the Mandrel that were not included in any patent applications. [Tr. Day 9 at 109:6-110:23; Tr. Ex. 1163]. Further, while it is true that the Mandrel was not included in Mr. Wagner's reasonable royalty calculation, the jury could still find that it was a valuable trade secret, given that it was covered by the NDA, not publically available, and necessary to construct CardiAQ's device.

Lastly, Neovasc is not entitled to a new trial on trade secret number 6. Trade secret number 6 was the development history of CardiAQ's TMVI device. In its trade secret disclosure, CardiAQ identified trade secret number 6 as:

The development history of CardiAQ's transcatheter replacement mitral valve prosthesis design, including the following: CardiAQ created an aortic valve prosthesis prototype designated as Rev. 4, which CardiAQ evaluated and tested. CardiAQ created a mitral valve prosthesis design designated as Rev. A. That Rev. A design evolved into a prototype designated as Rev. B, which CardiAQ evaluated and tested. That Rev. B design evolved into a prototype designated as Rev. C, which CardiAQ evaluated and tested. That Rev. C design evolved into a prototype designated as Rev. D, which CardiAQ evaluated and tested. That Rev. D design evolved into prototypes designated as the Rev. E series (including Rev. E2 through Rev. E4), which CardiAQ evaluated and tested.

[Tr. Ex. 1157 at 18]. According to Neovasc, this development history is not protectable as a trade secret because it does not satisfy the continuous use or unified process requirements under Massachusetts law. In addition, Neovasc claims that CardiAQ did not show that Neovasc improperly used or disclosed CardiAQ's development history.

Before and during its relationship with Neovasc, CardiAQ modified the design of its TMVI device. At the outset of the parties' relationship, both Mr. Ratz and Dr. Quadri told

Neovasc about CardiAQ's earliest TMVI work. [Tr. Day 3, 21:2-8; Tr. Ex. 1158 (showing Rev. A at p. 12, and Rev. B at p. 11)]. During their relationship, CardiAQ asked Neovasc to build frames with different designs, as CardiAQ modified the anchoring mechanism and other features of its device.

The jury, which was instructed on the Massachusetts continuous use requirement [Day 13 Tr. at 165:17-19], had a sufficient basis to conclude that CardiAQ continues to use trade secret 6 in the operation of its business. As it develops its TMVI device and works towards FDA approval, CardiAQ continues to use its past discoveries about what works and what does not. Its development history has influenced the current design of its TMVI device, and will likely influence any future modifications to it. [See, e.g., Tr. Day 4 at 110:10-111:4] (“Even as we encounter new challenges, if we look back and say, ‘How are we going to approach that, here is what we’ve done before,’ we know what not to do as we encounter something else.”). Likewise, the jury, which was also instructed on Massachusetts’ unified process requirement [Day 13 Tr. at 166:4-9], could reasonably conclude that CardiAQ’s development history constitutes a unified process. The development history described in trade secret 6 was for a single product. CardiAQ’s Revisions A through E were each steps in a defined progression of ideas. Each step informed the next, and there was a single purpose for the process—creating a functional TMVI device. Finally, CardiAQ presented sufficient evidence that Mr. Lane used both the dead ends and breakthroughs in CardiAQ’s development history to shape the design of the Tiara and to accelerate its development. As Neovasc itself admitted in a 2010 shareholder presentation, its “[i]ntimate understanding of what has and has not worked so far in the development of (percutaneous) valves” gave it a competitive advantage over other TMVI developers. [Tr. Ex.

608 at 4; see also Ex. 384 at 15] (“The Tiara program has benefited enormously from this pool of experience and talent that has evolved as we have worked with our partners.”).<sup>7</sup>

#### **IV. Inventorship**

The one issue that remains outstanding is CardiAQ’s inventorship claim. On November 12, 2013, the United States Patent and Trademark Office issued U.S. Patent No. 8,579,964 (the “’964 Patent”) to Neovasc. The ‘964 Patent, directed to a method of anchoring a valve into the heart, lists Randy Lane and Colin Nyuli, both Neovasc employees, as the inventors. The ‘964 Patent contains one independent claim (Claim 1) and 27 dependent claims (Claims 2-28). CardiAQ contends that Dr. Quadri and Mr. Ratz invented the subject matter of independent Claim 1 and dependent Claims 2 through 28 of the ‘964 Patent, either by themselves or in collaboration with Mr. Lane and Mr. Nyuli, and seeks an order, pursuant to 35 U.S.C. § 256, requiring Neovasc and the Director of the United States Patent and Trademark Office to take all steps necessary to correct the named inventor on the ‘964 Patent.

##### **a. Legal Standard**

35 U.S.C. Section 256 creates a cause of action in the district courts to correct the non-joinder of an inventor on a patent. Under Section 256, a district court “may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate

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<sup>7</sup> To the extent Neovasc seeks a new trial based on based on alleged inconsistencies in the trade secret verdict, its arguments here are also unavailing. As this Court instructed the jury, CardiAQ’s inability to prove misappropriation of one trade secret “does not mean that it has failed to do so with any of its other alleged trade secrets.” [Tr. Day 13, 164:16-165:1]. The jury’s determination of no misappropriation could hinge on one of any number of details (disclosure, use, continuous use, public disclosure, etc.), which are unique between each trade secret. For instance, the jury could have found that trade secrets 1-3 (the Rev. C, D, and E design prototypes) were no longer in continuous use, since CardiAQ has replaced them with updated prototypes. Each trade secret claim hinged on distinct facts, and the jury’s split verdict reflects an attentive and deliberative process.

accordingly.” 35 U.S.C. § 256. “Conception is the touchstone to determining inventorship.” Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Accordingly, “each joint inventor must generally contribute to the conception of the invention.” Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998). A co-inventor does not need to make a contribution to every claim of a patent. Id. Nor does a co-inventor need to contribute to the conception of all the limitations in a single claim. Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1361 (Fed. Cir. 2004). Rather, a joint inventor’s contribution must be “not insignificant in quality, when that contribution is measured against the dimension of the full invention.” Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., 776 F.3d 837, 845 (Fed. Cir. 2015) (quoting Fina Oil & Chem. Co., 123 F.3d at 1473), cert. denied, 136 S. Ct. 189 (2015), abrogated on other grounds by Halo Elecs., Inc. v. Pulse Elecs., Inc., 136 S. Ct. 1923 (2016). Each joint inventor needs to “perform only a part of the task which produces the invention.” Ethicon, Inc., 135 F.3d at 1460; see also Vanderbilt Univ. v. ICOS Corp., 601 F.3d 1297, 1303 (Fed. Cir. 2010) (“[T]he qualitative contribution of each collaborator is key—each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice.”) (quoting Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1229 (Fed. Cir. 1994)). To be a joint inventor, “[o]ne need not alone conceive of the entire invention, for this would obviate the concept of joint inventorship.” Fina Oil & Chem. Co., 123 F.3d at 1473.

Joint inventorship requires collaboration. “[C]o-inventors must collaborate and work together to collectively have a definite and permanent idea of the complete invention.” Vanderbilt Univ., 601 F.3d at 1308. The inventors must “have some open line of communication during or in temporal proximity to their inventive efforts.” Eli Lilly & Co., 376 F.3d at 1359. Patents issued by the USPTO are presumed to name the correct inventors and, as a result, “the

burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence.” Bard Peripheral Vascular, Inc., 776 F.3d at 845 (internal quotation marks omitted). Inventorship is a question of law. General Elec. Co. v. Wilkins, 750 F.3d 1324, 1329 (Fed. Cir. 2014). Nonetheless, the “determination of whether a person is a joint inventor is fact specific, and no bright-line standard will suffice in every case.” Fina Oil and Chem. Co., 123 F.3d at 1473.

Alleged co-inventors “must prove their contribution to the conception of the invention with more than their own testimony.” Gemstar-TV Guide Int’l, Inc. v. Int’l Trade Comm’n, 383 F.3d 1352, 1382 (Fed Cir. 2004). “The putative inventor must first provide credible testimony,” after which the Court applies a rule-of-reason analysis to determine whether the co-inventor’s testimony has been sufficiently corroborated. General Elec. Co., 750 F.3d at 1330. Corroborating evidence can include “contemporaneous records, oral testimony from someone other than the inventor, or other circumstantial evidence.” Univ. of Utah v. Max-Planck-Gesellschaft Zur Foerderung Der Wissenschaften e.V., No. 11-10484-PBS, 2015 WL 5698398, at \*5 (D. Mass. Sept. 28, 2015), appeal dismissed (Dec. 18, 2015).

#### **b. The ‘964 Patent**

Mr. Lane first sketched an idea for what would become the Tiara on October 20, 2009, and he first communicated to patent counsel his ideas for a transcatheter mitral valve replacement device in December 2009. [Tr. Day 9, 107:19-108:8]. On May 5, 2010, Mr. Lane and Neovasc filed provisional patent application No. 61/331,799, claiming the Tiara design [Tr. Day 9, 107:19-108:8; Tr. Ex. 565]. On April 28, 2011 Mr. Lane and Neovasc filed non-provisional application No. 13/096,572, which claimed priority to the May 5, 2010 application,



as well as to two intermittent provisional applications (Nos. 61/ 393,860 and 61/414,879). [Tr. Ex. 565]. On November 12, 2013, application No. 13/096,572 issued as the ‘964 Patent. Id.

Claim 1 of the ‘964 Patent claims a method of anchoring a prosthetic valve in a patient’s heart, said method comprising:

providing the prosthetic valve, wherein the prosthetic valve comprises an anchor having an atrial skirt, an annular region, a ventricular skirt, and a plurality of valve leaflets, wherein the ventricular skirt comprises a first trigonal anchoring tab disposed on an anterior portion of the ventricular skirt, wherein the anchor has a collapsed configuration for delivery to the heart and an expanded configuration for anchoring with the heart;

positioning the prosthetic valve in the patient’s heart;

expanding the atrial skirt radially outward so as to lie over a superior surface of the patient’s native mitral valve, and anchoring the atrial skirt against a portion of the atrium;

radially expanding the annular region of the anchor to conform with and to engage the native mitral valve annulus;

anchoring the first trigonal anchoring tab against a first fibrous trigone on a first side of an anterior leaflet of the native mitral valve, such that the anterior leaflet and adjacent chordae tendineae are captured between the trigonal anchoring tab and an anterior surface of the anchor; and

radially expanding the ventricular skirt thereby displacing the native mitral valve leaflets radially outward.

[ECF No. 293-11 at 60-61].

### **c. Discussion**

The parties agree that before getting to the inventorship question, the Court must engage in claim construction. The parties’ chief dispute, which was a central theme at trial, is the meaning of “trigonal anchoring tab” mentioned in Claim 1. Claim 1 describes a prosthetic valve, “wherein the ventricular skirt comprises a first trigonal anchoring tab” and involves “anchoring the first trigonal anchoring tab against a first fibrous trigone on a first side of an anterior leaflet

of the native mitral valve.” According to CardiAQ, the term “trigonal anchoring tab” means a tab *capable* of anchoring on a fibrous trigone when deployed. [ECF No. 512 at 2]. According to Neovasc, it means a tab *designed for* anchoring on a fibrous trigone when deployed. [ECF No. 535 at 9].

The following is a picture of the mitral valve from the ‘964 Patent:

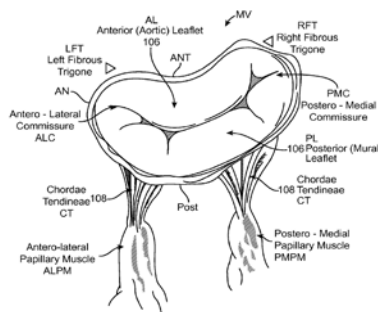


FIG. 5A

The figure shows that the mitral valve has two fibrous trigones, a left fibrous trigone and a right fibrous trigone. “AN” points to the mitral valve annulus. At trial and in their inventorship briefs, the parties have disputed whether the fibrous trigones are part of the native mitral valve annulus or not. According to Neovasc, the fibrous trigones are adjacent to, but separate from, the native mitral valve annulus. This is consistent with the ‘964 Patent, which stated that the fibrous trigones consist of “two regions adjacent an anterior portion of the annulus.” [Tr. Ex 115 at 53]. CardiAQ counters that the fibrous trigones are a continuous part of the annulus, and not separate from it. At trial, CardiAQ’s expert, Dr. Bavaria, testified that fibrous trigones are part of the native mitral annulus. [Tr. Day 6 at 34:23-35:22].

The Court does not need to resolve this anatomical dispute in order to define Claim 1. Regardless of whether the fibrous trigones are part of the annulus or not, the “trigonal anchoring tab” mentioned in Claim 1 is designed to anchor specifically on the fibrous trigones. In view of

the '964 Patent claim language and specification, "Anchoring the first trigonal anchoring tab against a first fibrous trigone on a first side of an anterior leaflet of the native mitral valve" means "positioning the trigonal anchoring tab in order to anchor it against a fibrous trigone on either the left or right side of the native anterior leaflet." CardiAQ's proposed construction would read the word "trigonal" out of Claim 1. A "trigonal anchoring tab" that anchors anywhere other than on a fibrous trigone is not described in the '964 patent, and CardiAQ's proposed construction is unduly broad. In re Man Mach. Interface Techs. LLC, 822 F.3d 1282, 1285 (Fed. Cir. 2016) (finding patent examiner erred in construing "thumb switch" broadly as "merely requir[ing] that a switch . . . be capable of being enabled/activated by a thumb but . . . not preclud[ing] another digit, i.e. index finger").

Even accepting this proposed claim construction, however, as well as all of the others proposed by Neovasc, CardiAQ has still demonstrated, by clear and convincing evidence, that it contributed to the conception of the '964 Patent and that Mr. Ratz and Dr. Quadri should be added as co-inventors.

While it is true that CardiAQ did not share with Neovasc any TMVI prototypes containing anchors specifically designed to anchor on the fibrous trigones, the prototypes that CardiAQ did discuss and share with Neovasc had equally spaced anchors, intended to anchor on the annulus generally. Given the number of anchors and size of the fibrous trigones, it was likely that at least one of CardiAQ's anchoring tabs would anchor against a fibrous trigone, but this was more a coincidence than on purpose.

A joint inventor, however, "does not need to contribute to every single element of every single claim in the patents—'some' contribution is sufficient." Rothschild v. Cree, Inc., 711 F. Supp. 2d 173, 204 (D. Mass. 2010) (citing 35 U.S.C. § 116); see also Ethicon, Inc., 135 F.3d at

1460 (each joint inventor “needs to perform only a part of the task which produces the invention”). “All inventors, even those who contribute to only one claim or one aspect of one claim of a patent, must be listed on [a] patent.” Vapor Point LLC v. Moorhead, 832 F.3d 1343, 1348–49 (Fed. Cir. 2016). To be a joint inventor, an individual must make a contribution to the claimed invention “that is not insignificant in quality, when that contribution is measured against the dimension of the full invention.” Fina Oil and Chem. Co., 123 F.3d at 1473.

Accordingly, even if Neovasc independently conceived of trigonal anchoring tabs designed to anchor on the fibrous trigone, CardiAQ still made a significant contribution to the conception of the ‘964 Patent. CardiAQ retained Neovasc to facilitate its TMVI development. During their ten-month business relationship, CardiAQ collaborated with Neovasc and shared with Neovasc the designs, prototypes, and development history of its device. Mr. Lane admits that he had never designed a TMVI device prior to working on the CardiAQ device, and his earliest sketches of a TMVI device do not appear until October 2009, months after he started working with Mr. Ratz and Dr. Quadri. [Tr. Day 9 at 60:25-61:3; Ex. 346 at 148]. The progression of TMVI ideas sketched in Mr. Lane’s notebook reflects a trend towards the designs of CardiAQ: Mr. Lane began in October 2009 with a grommet-style TMVI device with no distinct anchors, and he progressed to extended vertical anchors in March 2010, after Mr. Lane first received the Rev E design earlier, in February 2010. [Compare Ex. 346 at 148 with Ex. 346 at 160, 163; Tr. Day 9, 83:16-86:19]. Considering this sequence of events, as well as the similarities between the prototypes CardiAQ shared with Neovasc and the features of Claim 1, CardiAQ has shown by clear and convincing evidence that it unwittingly contributed to Mr. Lane’s inventive process. Even if Mr. Lane contributed some new ideas to the ‘964 Patent, Dr.

Quadri and Mr. Ratz performed “a part of the task which produces the invention.” See Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998).

Mr. Ratz and Dr. Quadri’s contribution to the invention and collaboration with Neovasc is corroborated not only by their own testimony, but also the testimony of Mr. Lane, the email communications between the parties [Tr. Exs. 1158-1219], and the physical prototypes of CardiAQ’s devices still in Neovasc’s possession. [Tr. Exs. 331-333]; see Gemstar-TV Guide Int’l, Inc. v. Int’l Trade Comm’s, 383 F.3d 1352, 1382 (Fed Cir. 2004) (alleged co-inventors “must prove their contribution to the conception of the invention with more than their own testimony”); Eli Lilly & Co., 376 F.3d at 1359 (noting that to establish collaboration, joint inventors must “have some open line of communication during or in temporal proximity to their inventive efforts”). The ‘964 Patent claims numerous features that were included in the prototypes and designs Mr. Ratz and Dr. Quadri shared with Neovasc, including a device that is delivered to a patient’s heart via a catheter, either through the apex of the heart or through the femoral vein; that once positioned in the patient’s native mitral valve, is allowed to expand and engages the native anatomy on both the atrial and ventricular sides of the annulus and includes an anterior side and a posterior side; and whose anchors extend between the native chordae tendinae, behind the free edge of the native mitral valve leaflets, and engage onto the native mitral annulus.

Neovasc relies on the prosecution history of the ‘964 Patent to argue that anchoring on the fibrous trigones was the key inventive aspect of the patent, and that because CardiAQ did not contribute to this novel part of the patent, it should not be named as a co-inventor. In a first Office Action dated June 4, 2013, the examiner found independent Claim 1 of the ‘964 Patent anticipated by a prior art reference, US Patent Publication No. 2006/0259136 to Nguyen et al

(“Nguyen”), that disclosed individual features similar to the elements of Claim 1. [Tr. Ex. 2779 at 1037-1045]. In response, Neovasc informed the Patent Office, and the Patent Office agreed, that the prior art reference did not teach “securing an anchoring tab against a first fibrous trigon[e].” [Ex. 2779 at 1085]. This, however, was not the only argument made by Neovasc and accepted by the Patent Office. In addition, Neovasc noted that the prior art disclosed the elements of Claim 1 in the context of a transcatheter *aortic valve* replacement device, not a mitral valve device. As Neovasc wrote to the Patent Office in response to the June 4, 2013 Office Action, “Nguyen discloses prosthetic valve for treating aortic stenosis or aortic regurgitation (para 001). Thus it is clear that Nguyen’s prosthetic valve is implanted in the patient’s aortic valve not the mitral valve as currently claimed. Nowhere in Nguyen is there teaching or suggestion that Nguyen’s prosthetic valve is implanted in the mitral valve. In fact terms such as ‘mitral valve,’ ‘chordae tendinae,’ ‘atrium,’ and ‘trigone’ do not even appear in Nguyen’s specification.” *Id.* at 1080-81. The Patent Office agreed, withdrawing its rejection of Claim 1 in part because “Nguyen falls to teach valve that engages native mitral valve annulus . . . .” *Id.* at 1085. Thus, the prior art not only lacked trigonal anchoring, but it also lacked a transcathetic mitral valve—exactly what CardiAQ shared with Neovasc—that engaged the native mitral valve annulus.

Neovasc also claims that a single prior art reference called Chau, a patent for a prosthetic mitral valve, disclosed all of the elements of the ‘964 patent contributed by CardiAQ. [ECF No. 535 at 5-6]. The parties agree, however, that the Chau reference was not public at the time Dr. Quadri and Mr. Ratz worked with Mr. Lane. Chau therefore does not detract from CardiAQ’s contribution to the ‘964 Patent. At the time Dr. Quadri and Mr. Ratz collaborated with Mr. Lane—sharing designs and prototypes of CardiAQ’s TMVI device—they were not “merely

explain[ing] . . . well-known concepts and/or the current state of the art.” Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998). Rather, in far more detail than they had ever made public, Dr. Quadri and Mr. Ratz shared with Neovasc the inventive process behind their TMVI project. In the context of 2009, when no one had ever built a successful transcatheter mitral valve device, Dr. Quadri and Mr. Ratz gave Neovasc a front-row view of CardiAQ’s TMVI development, thereby contributing to the conception of the ’964 Patent.

## **V. *Pro Hac Vice* Motions**

On October 19, 2016, Neovasc filed motions and a supporting memorandum [ECF Nos. 571-574] seeking the *Pro Hac Vice* admission of three additional attorneys. CardiAQ opposes the admission of these attorneys on grounds wholly unrelated to their fitness or qualifications. Because this Memorandum and Order resolves all of the other pending motions in the case, thereby effectively ending this litigation in the District Court, there is no reason for any attorney to “practice in this court” in this “particular case,” as required by Local Rule 83.5.3. The pending motions for Pro Hoc Vice admission will therefore be denied as moot.

## **VI. Conclusion**

For the reasons stated herein:

1. CardiAQ’s motion for enhanced damages [ECF No. 513] is GRANTED IN PART and Neovasc is ordered to pay \$21,000,000 in enhanced damages;
2. CardiAQ’s motion for injunctive relief [ECF No. 516] is GRANTED IN PART and the Court orders that:
  - a. Within 7 days of this Order, Neovasc must destroy all information that CardiAQ sent to Neovasc between June 2009 and April 2010, including emails and attachments thereto, CAD files, engineering drawings, animal test results, design

history information, as well as any work product that Neovasc generated that incorporates information contained in the foregoing, including the contents of any physical or electronic file that Neovasc may keep regarding CardiAQ, including the electronic CardiAQ folder referenced during trial (see Tr. Day 9 (Marko), 105:1-20; Ex. 1486 at 106:14-19). Neovasc must certify in writing that it has complied with this paragraph of the Order.

- b. Within 7 days of this Order, Neovasc must return to CardiAQ any CardiAQ prototypes, or portions thereof, that CardiAQ provided to Neovasc and that Neovasc still has in its possession, custody, or control, including but not limited to prototypes fabricated by Neovasc to test any CardiAQ prototype design.<sup>8</sup>
3. Neovasc's motion for a new trial on damages [ECF No. 522] is DENIED;
4. Neovasc's motion for a new trial on trade secrets 4-6 [ECF No. 521] is DENIED;
5. CardiAQ has shown by clear and convincing evidence that Dr. Quadri and Mr. Ratz contributed to the conception of U.S. Patent No. 8,579,964 and the Court therefore orders that Dr. Quadri and Mr. Ratz be added as inventors of U.S. Patent No. 8,579,964; and
6. Neovasc's motions for the *Pro Hac Vice* admission of new attorneys [ECF Nos. 571-573] are DENIED as MOOT.

**So Ordered.**

October 31, 2016

/s/ Allison D. Burroughs  
ALLISON D. BURROUGHS  
U.S. DISTRICT JUDGE

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<sup>8</sup> Paragraphs a and b shall not apply to materials produced in, or generated by, this lawsuit and maintained by counsel of record or any other third party permitted by the Protective Order entered in this case [ECF No. 92] and used in accordance with that Order.